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No. 00-1766

IN THE
Supreme Court of the United States

ELIZABETH KEMP AND CLIFFORD KEMP,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

REPLY BRIEF FOR PETITIONERS

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REPLY BRIEF FOR PETITIONERS

The petition presents an important federal preemption question under the Medical Device Amendments ("MDA") that has divided the federal and state appellate courts. The deep split in authority is best exemplified by decisions of the Eleventh Circuit and the Sixth Circuit below that have arrived at diametrically opposed legal conclusions on the question presented in cases involving the same defendant and the same medical device. *See* Petition at 1. In opposition, respondent Medtronic, Inc. asserts that review should be denied because petitioners Elizabeth and Clifford Kemp did not properly preserve their claims and, even if they had, the split in authority does not warrant this Court's attention. As explained below, Medtronic's arguments are incorrect and the Court should grant the petition.

I. THE KEMPS HAVE PRESERVED THEIR PRINCIPAL PRODUCT LIABILITY AND NEGLIGENCE CLAIMS, ALL OF WHICH WOULD BE AFFECTED BY A RULING OF THIS COURT ON THE QUESTION PRESENTED.

As the Sixth Circuit below stated (8a), the courts are "sharply divided" on whether state-law product-liability and negligence claims, such as those alleging defective design and manufacture and failure to warn, are preempted by the MDA, where the device in question was granted pre-market approval ("PMA") by the Food and Drug Administration ("FDA"). Medtronic's principal argument against review is that the Kemps did not preserve any such claims in the Sixth Circuit and thus those claims are not before this Court. Medtronic is flatly incorrect.

The Kemps' complaint contained multiple causes of action, including "strict liability based on defective manufacture, design, and warning" (45a), negligent testing, manufacture, and design of the 4004M lead (45a), a separate

count alleging that "Medtronic failed to warn the Plaintiffs of dangerous risks involved in the use of the 4004M lead" (45a), and another alleging that Medtronic breach implied warranties in its design and marketing of the lead. 46a; *see generally* Complaint in *Kemp v. Medtronic, Inc.*, No. C-1-97-0103 (S.D. Ohio filed Jan. 24, 1997). On January 12, 1999, the district court granted summary judgment to Medtronic on the Kemps' claims of defective manufacture (57a), defective design (60a), failure to warn (60a-61a), and implied warranty (68a) on federal preemption grounds. At the same time, the district court also granted the Kemps leave to amend their complaint to make additional allegations in support of a negligence per se claim (67a).

The Kemps then filed an amended complaint regarding the negligence per se claim and also reiterated each of their general causes of action. The Kemps asked "the [district] Court to revisit its [earlier preemption] ruling" regarding the general state-law design, manufacturing, failure to warn, and implied warranty claims (80a), relying on the Eleventh Circuit's recent ruling in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), which also involved Medtronic's 4004M lead and held that the MDA does not preempt such claims. On April 30, 1999 (70a), the district court granted summary judgment to Medtronic on the negligence per se claim and rejected the Kemps' request for reconsideration. The district court entered judgment for Medtronic on all claims and dismissed the case with prejudice (82a).

Thereafter, the Kemps filed a notice of appeal, which explicitly appealed from the district court's January 12 order on the general product liability and negligence claims as well as the April 30 ruling that had reaffirmed that holding and rejected the negligence per se claim.. *See* Notice of Appeal ¶¶ 1, 3 in *Kemp v. Medtronic, Inc.*, No. C-1-97-0103 (S.D. Ohio filed May 28, 1999). The Sixth Circuit affirmed the district court's

summary judgment ruling in its entirety. It explicitly noted the Kemps' general product liability and negligence claims (54a), and did not remotely suggest that the Kemps had waived those claims. The court then made the "threshold" determination that the PMA process establishes "specific federal requirements" that have preemptive effect under this Court's decision in *Lohr* (15a-22a). The Sixth Circuit thus "agree[d]" with Medtronic that "the design, manufacturing processes, and labeling" involved in the PMA process are federal requirements that have preemptive effect (21a-22a), and it explicitly rejected the Eleventh Circuit's contrary ruling in *Goodlin*. 18a. Thereafter, in a section labeled "Plaintiffs' Claims," the Sixth Circuit dealt only with the Kemps' negligence per se, fraud on the FDA, and failure to warn claims (22a-38a). If taken in isolation, this portion of the court of appeals' opinion could lead a reader to believe that the Kemps had pled *only* those claims, but, as indicated above, that would be plainly wrong and the preceding portions of the Sixth Circuit's opinion effectively reject the Kemps' design and manufacturing defect claims on the ground that the PMA process establishes federal preemptive "requirements."

In any event, regardless of how the Sixth Circuit parsed the Kemps' claims, there is no doubt that the Sixth Circuit's judgment affirmed the district court's rulings in their entirety, including the rulings rejecting the Kemps' general product liability and negligence claims, on preemption grounds. Recognizing that critical fact, Medtronic asserts that the Kemps raised only the negligence per se, fraud-on-the-FDA, and failure-to-warn claims in their Sixth Circuit brief. Based on that premise, Medtronic maintains that, because the Sixth Circuit resolved each of those claims on non-preemption grounds, the Kemps are seeking an advisory opinion on MDA preemption that would have no effect on their claims. Opposition at 15.

The premise of Medtronic's argument is simply wrong. The Kemps vigorously pursued *all* of their claims in the Sixth Circuit. Indeed, the *first* argument in the Kemps' appellate brief states that "There is No Preemption Immunity for a Manufacturer of a Medical Device by Virtue of Approval of a PMA Supplement Application." Brief of Plaintiffs-Appellants at 34 in *Kemp v. Medtronic, Inc.*, No. 99-3720 (filed Jan. 11, 2000). The Kemps maintained that *none* of their claims is preempted "Because there are no Federal Requirements Applicable to the 4004/M as a Result of the PMA Supplement Application Process." *Id.* at 40. In making this argument, the Kemps relied on the Eleventh Circuit's decision in *Goodlin*, *id.* at 41, which held that the PMA process does not establish specific federal requirements that preempt state-law design, manufacturing, and failure-to-warn claims. The Kemps argued that "[t]he FDA's issuance of a generic form approval letter does not mean that the FDA has established specific design and manufacturing requirements." *Id.* at 44. Thus, because the FDA did not promulgate "federal regulations regarding the manufacture and design of pacemaker leads," "there is no preemption immunity under Section 360k." *Id.* at 45.

The Kemps also argued in the Sixth Circuit that *none* of their claims is preempted because their state product-liability and negligence claims are not sufficiently specific to trigger preemption under *Lohr*. *Id.* at 45. The Kemps ended this argument by stating that their claims are "indisputably based on duties of general applicability of Ohio common law and Ohio's product liability act," *id.* at 48, and therefore are not preempted, an explicit reference to their "claim under Ohio law for strict liability based on defective manufacture, design, and warning." *See* 45a & n.2.

It was only *after* the Kemps maintained that none of their claims is preempted, beginning on page 52 of their appellate brief, that they turned to their alternative argument:

"Regardless of Whether the FDA's Approval of the 4004/M PMA Supplement Establishes Specific Federal Requirements, Medtronic Was Not Entitled To Summary Judgment on All of Plaintiffs' Claims." The Kemps then explained why, even if there was some preemption, their claims based on negligence per se, fraud on the FDA, and failure to warn of post-approval information are not preempted. *See id.* at 52-63. Thus, in concluding their brief, the Kemps asked the Sixth Circuit to reverse the district court's order "on *all* of Plaintiffs' claims." *Id.* at 63 (emphasis added).

In sum, the Kemps' general product liability and negligence claims — the very kinds of claims about which the federal and state courts are divided in MDA preemption cases — were argued to the Sixth Circuit and dismissed as a result of the Sixth Circuit's judgment. Therefore, they are properly before this Court.[1]

II. THE QUESTION PRESENTED INVOLVES A DEEP AND UNRESOLVED SPLIT IN AUTHORITY THAT CALLS FOR RESOLUTION BY THIS COURT AT THIS TIME.

Medtronic contends that the Court should deny review because this Court's recent decision in *Buckman Company v. Plaintiffs' Legal Committee*, 121 S. Ct. 1012 (2001), may alter

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[1]Medtronic's assertion that the Kemps preserved their failure-to-warn claim only to the extent that it alleged a failure to warn of information known to Medtronic after approval of the 4004M lead is particularly odd. The Sixth Circuit held that the Kemps did not adequately plead that aspect of the claim and therefore did not reach the preemption issue regarding it (38a). However, the Sixth Circuit also held that the claim that Medtronic failed to warn of information known at the time of the 4004M's approval is preempted by the MDA (37a). That claim is therefore properly before this Court.

the legal terrain and because the split in authority among the lower courts in not as serious as the Kemps maintain. Neither contention is persuasive.

A. Medtronic asserts that the Court should defer review because *Buckman* "may assist [lower] courts" in resolving the question presented. Opposition at 17. Medtronic ignores the key reason why *Buckman* is irrelevant here: In holding that a fraud-on-the-FDA claim is impliedly preempted by federal law, *Buckman* explicitly distinguished claims, such as those at issue here, that "rely[ ] on traditional state tort law which had predated the federal [MDA] enactments in question." 121 S. Ct. at 1020.

Beyond that basic omission, Medtronic makes three points related to *Buckman*, none of which has merit. First, it notes that in *Buckman,* "as in *Lohr*," the Court "stressed" the difference between the PMA process and the 510(k) process. Opposition at 17. Actually, *Buckman* mentioned that point only in passing, 121 S. Ct. at 1017; *Buckman* had nothing to do with the PMA process because the device there was a 510(k), not a PMA, device. *Id.*

Second, Medtronic claims that *Buckman* clarified that, under *Lohr*, only "certain" state-law causes of action that parallel federal requirements may go forward. Opposition at 17. That supposed clarification also has nothing to do with this case, because the Kemps are not pursuing claims that purport to parallel federal requirements, *see* Petition at 8 n.2; instead, they rely exclusively on general state-law claims regarding manufacturing and design defect and failure to warn. Equally important, the principal cases reflecting the deep divide among the lower courts also involve those kinds of claims. S*ee, e.g., Goodlin*, 167 F.3d at 1369; *Oja v. Howmedica*, 111 F.3d 782, 784-85 (10th Cir. 1997); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1151 (Ill. 1999); *Martin v. Medtronic, Inc.*, __ F.3d __, __, 2001 WL 682097, *1 (5th Cir. 2001).

Thus, none of those precedents could possibly be affected by *Buckman*'s comment regarding state-law causes of action that parallel federal requirements.

Third, Medtronic relies on *Buckman*'s statement that a state-law fraud-on-the-FDA claim would disrupt the balance that Congress was trying to achieve under the MDA. Opposition at 17. We fail to see how that point relates to the question presented here — whether 21 U.S.C. 360k(a) expressly preempts the Kemps' claims based on "traditional state tort law." *Buckman*, 121 S. Ct. at 1020. In this regard, it is important to consider what was at issue in *Buckman*. The plaintiff in *Buckman* relied solely on a fraud-on-the-agency theory, rather than a traditional tort theory, because the defendant was not the device manufacturer, but rather a regulatory consultant who had no relationship with the medical device patients or their physicians. The theory of the case was unrelated to whether the product was properly designed or manufactured or accompanied by appropriate warnings, but was premised entirely on the notion that the product would not have been marketed if not for the consultant's fraudulent submissions to the FDA. Thus, the Court's concern about the balance struck by Congress related to the potential for interference with the internal workings of the FDA, *id.*, not with the independent tortious conduct of device manufacturers in their interactions with device users and physicians, as is the case here. Moreover, the Court's ruling was based solely on *implied preemption* principles and did not even discuss whether a fraud-on-the-FDA claim, let alone the "traditional state law tort" claims at issue here, is preempted by the MDA's express preemption provision, 21 U.S.C. 360k(a). Indeed, *Buckman*'s only reference to section 360k(a) is in a footnoted sentence stating that the Court would *not* consider the question whether a fraud-on-the-FDA claim is expressly preempted. 121 S. Ct.

at 1017 n.2. In sum, the fraud-on-the-FDA ruling in *Buckman* has no bearing on the question presented here.[2]

B. Even farther afield is Medtronic's speculation that courts that have rejected preemption may revisit their no-preemption holdings, and that therefore this Court should deny review because the split in authority will go away. Absent a decision of this Court finding preemption on the question presented, there would be no lawful basis for such an about-face. Indeed, we know of no case in the Tenth Circuit (where *Oja* prevails) or in the Eleventh Circuit (where *Goodlin* prevails) in which the defendant device manufacturer is arguing that *Buckman* or some other development requires that circuit precedent be set aside, and presumably Medtronic — the world's largest device manufacturer and a frequent litigant — would have brought such cases to this Court's attention if there were any. In the federal system, the no-preemption circuit precedents may only be reversed en banc. That would require the defendant to lose a trial on the merits, appeal on preemption grounds, and convince an en banc court to overrule existing

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[2] Medtronic contends that recent decisions demonstrate that *Buckman* is having an effect on express preemption analysis under the MDA. Just the opposite is true. Despite Medtronic's suggestion to the contrary, Opposition at 17-18, the Fifth Circuit's recent decision in *Martin,* 2001 WL 682097 — which involved the exact same issue as presented here regarding the 4004M lead — did not rely on *Buckman* in any respect. Similarly, *Brooks v. Howmedica, Inc.*, 226 F.3d 966 (8th Cir. 2001), involved solely the question whether a traditional state-law failure-to-warn claim is expressly preempted by section 360k(a). The fact that rehearing en banc was granted in *Brooks* the day after *Buckman* was decided, *see* Opposition at 18, is obviously happenstance, unless we are to believe that, sensing a need to act immediately, the full complement of Eighth Circuit judges read this Court's decision, conferred, and granted the en banc petition within 24 hours.

circuit precedent. Thus, the notion that this Court should deny review on the ground that the Tenth and Eleventh Circuits will reverse themselves, eliminating any federal circuit conflict, does not hold water. The chance that the state courts will overrule their no-preemption holdings, *see* Petition at 16, 18-19, is even more remote, because those courts have already heard the matter en banc and are extremely unlikely to reverse course absent an authoritative ruling on the express preemption issue presented in this petition.[3]

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[3]Medtronic's argument that the current split in authority is not significant, Opposition at 18-23, is fully answered by the petition (at 14-19). Although Medtronic purports to deny a significant split, Opposition at 18, Medtronic's main thrust is actually a critique on the merits of the key decisions with which it disagrees. *Id.* at 18-23. That the courts have taken differing views on the merits, however, only underscores the need for review. *See infra* Part III. As to the split in authority, we reiterate that, in December 1997, *before* the Eleventh Circuit's decision in *Goodlin* and the Illinois Supreme Court's decision in *Weiland*, the Solicitor General maintained that the "current division" in the courts would have called for review by this Court, except for unusual circumstances not present here. *See* Petition at 23 (discussing Solicitor General's amicus brief in *Smith Industries Medical Systems v. Kernats*, No. 96-1405). Medtronic's assertion that the government's position on the merits in *Kernats* was based on the pendency of a now-withdrawn proposed FDA regulation is flatly incorrect. The Solicitor General argued at length that the no-preemption decision in *Kernats* was correct. That merits argument was unrelated to the proposed regulation, *see* United States Brief in *Kernats*, at 14-18, which was discussed at the very end of the brief only as a reason to deny review. *Id.* at 19-20.

III. THE RULING BELOW ON THE MERITS UNDERSCORES THE NEED FOR REVIEW.

The petition briefly explains why the ruling below on the merits is inconsistent with the text and purpose of the MDA and this Court's decision in *Lohr*. Petition at 20-22. Medtronic, of course, argues that the ruling below is correct. Opposition at 20-23. The parties' disagreements are quite stark. For instance, while Medtronic argues that FDA pre-market approval transforms all specifications of the manufacturer's application into preemptive federal requirements, Opposition at 24, the Kemps maintain that such specifications originate with the manufacturer, not FDA, and thus are not specific federal requirements that have preemptive force (as contrasted with certain FDA regulations applicable to particular devices). Petition at 21. The petition and opposition reveal the parties' drastically different understanding of the law and the significance of the facts concerning approval of the 4004M lead. If this Court grants review, there will be time enough to reply to Medtronic's merits arguments in detail. However, for present purposes, the depth of the disagreement on the merits only underscores the need for review. As is evident from the parties' submissions, some courts have sided largely with the Kemps on the merits and others largely with Medtronic. Their positions are irreconcilable and can only be resolved through this Court's intervention.

CONCLUSION

For the reasons stated above and in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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